UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/805,806	03/22/2004	Jeffrey S. Kiel	455-026	9957

1009 7590 08/08/2006

KING & SCHICKLI, PLLC
247 NORTH BROADWAY
LEXINGTON, KY 40507

EXAMINER
OH, TAYLOR V

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/805,806	KIEL ET AL.	
	Examiner	Art Unit	
	Taylor Victor Oh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/12/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The Status of Claims

Claims 1-19 are pending.

Claims 1-19 have been rejected.

DETAILED ACTION

Priority

1. It is noted that this application claims benefit of 60/457,399 (03/25/03).

Drawings

2. None.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim sets forth the treatment of all the conditions of the central nervous system. However, the specification never has shown the actual experimental data for treating all the conditions of the central nervous system, but has merely mentioned that Gabapentin is a neuroleptic agent as adjunctive therapy in the treatment of central nervous system conditions in mammalian subjects , such as partial seizures, epilepsy, faintness attacks, hypokinesis, pain associated with shingles, and cranial trauma.

The followings are some of the diseases based on the conditions of the central nervous system:

> Alzheimer Disease - Arachnoiditis - Brain Abscess - Brain Diseases - Brain Ischemia - Central Nervous System Diseases - Central Nervous System Infections - Cerebral Palsy - Cerebrovascular Disorders - Corticobasal Ganglionic Degeneration (CBGD) (not on MeSH) - Creutzfeldt-Jakob Syndrome - Dandy-Walker Syndrome - Dementia - Dementia, Vascular - Encephalitis - Encephalitis, Herpes Simplex - Encephalomyelitis - Epilepsy - Essential Tremor - Friedreich Ataxia - Gerstmann-Straussler-Scheinker Disease - Hallervorden-Spatz Syndrome - Huntington Disease - Hydrocephalus - Hydrocephalus, Normal Pressure - Hypoxia, Brain - Insomnia, Fatal Familial - Ischemic Attack, Transient - Kuru - Landau-Kleffner Syndrome - Lewy Body Disease - Machado-Joseph Disease - Meige Syndrome - Meningitis, Bacterial - Meningitis, Viral - Migraine Disorders - Movement Disorders - Multiple System Atrophy - Myelitis - Olivopontocerebellar Atrophies - Parkinson Disease - Parkinsonian Disorders - Poliomyelitis - Postpoliomyelitis Syndrome - Prion Diseases - Pseudotumor Cerebri - Shy-Drager Syndrome - Spasms, Infantile - Spinal Cord Diseases - Supranuclear Palsy, Progressive - Syringomyelia - Thalamic Diseases - Tic Disorders - Tourette Syndrome - Uveomeningoencephalitic Syndrome -

According to the specification, there is no tangible evidence to support that Gabapentin will cure all the above diseases. Furthermore, the CNS disorders can be caused by many different factors: inherited genetic abnormalities, problems in the immune system, injury to the brain or nervous system , diabetes , neuro-chemical imbalance (neurotransmitters), and etc. The specification falls short because data essential for

how all the CNS disorders can be treated by means of administering Gabapentin to any patient with any CNS disorders.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

The Nature of the Invention

The nature of the invention in claims 1,4,6,11,17 is the method of treating a condition of the central nervous system in a mammalian subject by administering Gabapentin.

The State of the Prior Art

The state of the prior art is that according to Drugs of Future (vol.9 no. 6, 1984p. 418-419),US Patent Nos. 5,095,148, 4,024,175, 4,152,326, and 5,132,451, Gabapentin has been used as an anticonvulsant to treat a patient. US Patent No. 5,068,413 describes that it is useful in therapy of certain cerebral disorders such as faintness attacks, hypokinesis and cranial traumas. Bennett et al (J Clin psychopharmacol. 1997, Arr., 17(2):141-2) discloses gabapentin for treatment of bipolar and schizoaffective disorders. Bozikas et al (Prog Neuropsychopharmacol Biol Psychiatry, 2002 Jan. 26 (1),

:197-9) teaches treatment of alcohol withdrawal with gabapentin. And Brannon et al (Can J Psychiarty, 200 Feb; 45(1):84) has indicated that Gabapentin can be used for treating post-traumatic stress disorder.

However, there is no conclusive indicator that Gabapentin can be used for treating all the CNS diseases except some of CNS diseases.

The predictability or lack thereof in the art

The instant claimed invention is highly unpredictable as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize that the exact mechanism of gabapentin remains uncertain except that it is shown in recent data to be a selective agonist at the gb1a-gb2 heterodimer and post-synaptic $GABA_B$ receptor would result in only the specific receptor site of the brain cells; this kind of treatment can not be translated to the possible treatment of all the CNS diseases in regards to their therapeutic effects.

Hence, in the absence of a showing of correlation between all the CNS diseases claimed and treatment by the Gabapentin compound, one of skill in the art is unable to fully predict possible results from the administration of the claimed Gabapentin compound due to the unpredictability of the role of a selective agonist at the gb1a-gb2

heterodimer and post-synaptic $GABA_B$ receptor, i.e. whether promotion or inhibition would be beneficial for the treatment of all the CNS diseases.

There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The amount of direction or guidance present

The direction present in the instant specification is that the Gabapentin compound can treat all the CNS diseases. However, the specification is silent and fails to provide guidance as to whether the CNS diseases listed (page 3, lines 21-23) requires the action of the Gabapentin for treatment, i.e. the specification fails to provide a correlation between the disease listed and the role of the Gabapentin. Also, there is no direction and guidance for the role of the Gabapentin for the treatment of all the CNS diseases.

The presence or absence of working examples

There is no working example for any of CNS diseases ,such as partial seizures, epilepsy, faintness attacks, hypokinesis, pain associated with shingles, and cranial trauma in the specification. Also, the Gabapentin compound disclosed in the specification has no pharmacological data regarding the treatment of any of CNS diseases except mentioning that it can treat a condition of the central nervous system in a mammalian subject and the specification has no data on the possible treatment of all the CNS diseases that require the action of the Gabapentin compound. Also, the

specification fails to provide working examples as to how the listed diseases in the above can be treated by the action of the Gabapentin, i.e. again, there is no correlation between the diseases listed and the role of the Gabapentin.

The breadth of the claims

The breadth of the claims is that the Gabapentin can treat any condition of the central nervous system in a mammalian subject without regards as to the affect of the action of the Gabapentin on the stated disease.

The quantity of experimentation needed

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine what CNS diseases would be benefited by the action of the Gabapentin.

The level of the skill in the art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which one of CNS diseases would benefit from this activity.

Thus, the specification fails to provide sufficient support of the broad use of the Gabapentin compound for the treatment of all the CNS diseases. As a result, necessitating one of skill to perform an exhaustive search for which CNS diseases can be treated by the Gabapentin compound in order to practice the claimed invention.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001 , states that " a patent is not a hunting license. It is not a reward for search , but compensation for its

successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which diseases can be treated by the compound encompassed in the instant claims, with no assurance of success.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*** 4/4/06